To: Doa, Maria[Doa.Maria@epa.gov]

Cc: Canavan, Sheila[Canavan.Sheila@epa.gov]; Wolf, Joel[Wolf.Joel@epa.gov]; Kramek,

Niva[kramek.niva@epa.gov]
From: Krasnic, Toni

Sent: Fri 11/17/2017 5:42:02 PM

Subject: FW: TCE

Hi Maria,

Please see the email request below and let me know your preference on how to respond.

Thanks,

Toni Krasnic

Existing Chemicals Branch

EPA/OCSPP/OPPT/CCD/ECB

WJC East, 4134D | (202) 564-0984

From: Dourson, Michael

Sent: Friday, November 17, 2017 12:37 PM **To:** Krasnic, Toni <krasnic.toni@epa.gov>

Cc: Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>;

Morris, Jeff < Morris.Jeff@epa.gov>

Subject: TCE

Dear Toni Krasnic

I would be interested in more information regarding this topic.

Visit at Integer facility on use of TCE in vapor degreasing in the manufacture of medical devices: On October 19, 2017, CCD, CESSD, and RAD staff visited Integer's facility in Minneapolis, MN. Integer was formed from the merger of Greatbatch, Lake Region Medical, and Electrochem, and specializes in the design and development of medical devices and power solutions for the medical and non-medical markets. EPA toured Integer's facility where they make various medical devices, for a demonstration of open-top vapor degreasing, spray degreasing, enclosed vapor degreasing, and aqueous degreasing. Integer also provided a tour of their manufacturing process of medical devices and showed samples of their actual medical products. Additionally, they discussed the research and testing they've done on non-TCE alternatives and argued that there are no effective alternatives available that can clean all of the medical devices they produce and are compatible with lubricants they use. Validation by FDA of new cleaning process in medical device manufacturing process, which typically takes about 3 years, was also highlighted as a major challenge to transitioning to TCE alternatives

Thanks!
Michael
L. Dourson, PhD., DABT, FATS, FSRA
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